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I, JANENE PEISKER, TEAM LEADER EXAMINATION SUPPORT AND SALES hereby certify that annexed is a true copy of the Provisional specification in connection with Application No. 2002952997 for a patent by COCHLEAR LIMITED as filed on 29 November 2002.

WITNESS my hand this
Twenty-seventh day of May 2005

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PROVISIONAL SPECIFICATION

Invention Title:

Pharmaceutical delivery device for a cochlear implant electrode array

The invention is described in the following statement:

Field of the Invention

The present invention relates to an implantable device and, in particular, to an implantable device for use in delivering pharmaceuticals to the site of a cochleostomy following implantation of a cochlear electrode assembly.

Background of the Invention

Hearing loss, which may be due to many different causes, is generally of two types, conductive and sensorineural. Of these types, conductive hearing loss occurs where the normal mechanical pathways for sound to reach the hair cells in the cochlea are impeded, for example, by damage to the ossicles. Conductive hearing loss may often be helped by use of conventional hearing aid systems, which amplify sound so that acoustic information does reach the cochlea and the hair cells.

In many people who are profoundly deaf, however, the reason for deafness is sensorineural hearing loss. This type of hearing loss is due to the absence of, or destruction of, the hair cells in the cochlea which transduce acoustic signals into nerve impulses. These people are thus unable to derive suitable benefit from conventional hearing aid systems, because there is damage to or absence of the mechanism for nerve impulses to be generated from sound in the normal manner.

It is for this purpose that cochlear implant systems have been developed. Such systems bypass the hair cells in the cochlea and directly deliver electrical stimulation to the auditory nerve fibres, thereby allowing the brain to perceive a hearing sensation resembling the natural hearing sensation normally delivered to the auditory nerve.

Cochlear implant systems have typically consisted of two key components, namely an external component commonly referred to as a processor unit, and an implanted internal component commonly referred to as a receiver/stimulator unit. Traditionally, both of these components have cooperated together to provide the sound sensation to an implantee.

The external component has traditionally consisted of a microphone for detecting sounds, such as speech and environmental sounds, a speech processor that converts the detected sounds and particularly speech into a coded signal, a power source such as a battery, and an external antenna transmitter coil.

The coded signal output by the speech processor is transmitted transcutaneously to the implanted receiver/stimulator unit situated within a recess of the temporal bone of the implantee. This transcutaneous transmission occurs through use of an inductive coupling provided between the external antenna transmitter coil which is positioned to communicate with an implanted antenna receiver coil provided with the receiver/stimulator unit. This communication serves two essential purposes, firstly to transcutaneously transmit the coded sound signal and secondly to provide power to the implanted receiver/stimulator unit. Conventionally, this link has been in the form of a radio frequency (RF) link, but other such links have been proposed and implemented with varying degrees of success.

The implanted receiver/stimulator unit typically includes the antenna receiver coil that receives the coded signal and power from the external processor component, and a stimulator that processes the coded signal and outputs a stimulation signal through a lead to an intracochlea electrode assembly which applies the electrical stimulation directly to the auditory nerve producing a hearing sensation corresponding to the original detected sound.

The electrode assembly is typically implanted through a cochleostomy formed in the cochlea and comprises an array of electrodes, with each electrode being arranged and constructed to deliver a cochlea stimulating signal within a preselected frequency range to an appropriate cochlea region. The electrical currents and electric fields from each electrode stimulate the cilia disposed on the modiolus of the cochlea. Several electrodes may be active simultaneously.

There have been a number of proposals for delivering bio-active substances to the cochlea that are beneficial in promoting acceptance of the electrode assembly within the cochlea and/or assisting in the function of the

auditory nerve. One such proposal is described in the present applicant's International Application No PCT/AU01/01479 which describes use of a lumen within the electrode assembly that delivers bio-active substances directly within the cochlea following implantation of the assembly.

The present invention provides an alternative system for delivering beneficial bio-active substances to the region of the cochlea of a patient and particularly an implantee of a cochlear implant.

Any discussion of documents, acts, materials, devices, articles or the like which has been included in the present specification is solely for the purpose of providing a context for the present invention. It is not to be taken as an admission that any or all of these matters form part of the prior art base or were common general knowledge in the field relevant to the present invention as it existed before the priority date of each claim of this application.

Summary of the Invention

Throughout this specification the word "comprise", or variations such as "comprises" or "comprising", will be understood to imply the inclusion of a stated element, integer or step, or group of elements, integers or steps, but not the exclusion of any other element, integer or step, or group of elements, integers or steps.

It is a preferred feature of the present invention to provide a device that is adapted to assist the cochlea in its recovery from trauma following the insertion of an electrode assembly therein. The present invention is equally applicable to conventional electrode assemblies and electrode assemblies which are designed to conform with the inner wall of the cochlea.

According to a first aspect, the present invention is an implantable tissue-stimulating device comprising:

a lead;

a resiliently flexible elongate member extending from the lead and having a proximal end and a distal end and at least one electrode mounted thereon between said proximal and distal ends for delivering electrical stimulation; and

a bio-active substance delivery means adapted to deliver at least one bio-active substance to the implantee at a location spaced from the distal end of the member during and/or following implantation of the device;

wherein the substance delivery means comprises a body defining a chamber and an outlet in communication with the chamber through which bio-active substance can exit the body and further wherein the body is relatively slidably mounted to the lead of the device.

In a preferred embodiment of this invention, the device is a cochlear implant electrode assembly, with the elongate member adapted to be inserted through a cochleostomy formed in the cochlea and positioned therein. In this embodiment, the outlet of the substance delivery means is preferably positionable outside and adjacent the cochleostomy site. In this embodiment, the body is preferably relatively slidable along the lead until it reaches a location along the lead that results in it being positioned just outside the cochleostomy following implantation.

In a preferred embodiment, the lead can be provided with a stop means that prevents the body of the substance delivery means from being moved relatively past the stop means and onto the elongate member. In another embodiment, the stop means can comprise a stop member that, once engaged with the body, prevents subsequent slidable movement of the collar relative to the lead in either direction.

In a preferred embodiment, the elongate member is formed from a suitable biocompatible material.

In a further embodiment, the body of the substance delivery means comprises an annular member that is positioned around the lead of the stimulating device. The body preferably has an outer surface. In another embodiment, the annular member can comprise a cylindrical collar member. In this embodiment, the body preferably has a longitudinal axis. In one embodiment, the body can be symmetrical or non-symmetrical about the longitudinal axis.

In another embodiment, the body can comprise a portion of a ring, such as a half-pipe.

The annular member can comprise a first portion and a second portion, the second portion having an outer diameter less than that of the first diameter. In one embodiment, both the first portion and the second portion can be cylindrical. In this case, the outer surface preferably has a step between the first and second portion. The outer diameter of the first portion can be about twice that of the elongate member. In one embodiment, the first portion can have an outer diameter of about 1.2mm.

In yet a further embodiment, the body can have a proximal end and a distal end. The proximal and distal ends can be at least substantially parallel or parallel.

In a further embodiment, the outlet of the body can be positioned in the distal end of the body. In a still further embodiment, the body can have an inlet in the proximal end of the body. The inlet and outlet are preferably in communication, such as fluid communication, with each other.

In a still further embodiment, the outlet of the body can comprise an annular opening in the distal end of the body. The chamber within the body can extend back into the body from the outlet. Where the outlet is an annular opening, the chamber can also be annular in form and so comprise a cylindrical chamber having an outer and inner surface and extending back into the body from the outlet.

In a still further embodiment, the annular chamber has a region where the outer wall of the chamber moves away from the longitudinal axis or the lead passing through the body as the chamber extends back into the body from the outlet. In this embodiment, the inner wall of the chamber can also move away from the longitudinal axis or the lead in said region. In one embodiment, the chamber can have a frusto-conical portion. In yet a further embodiment, the chamber can comprise a portion distal the outlet that is also cylindrical in form. In this embodiment, the inlet preferably comprises a pipe extending from the

proximal end of the body into the chamber. The inlet is preferably adjacent the outer wall of the body.

In a still further embodiment, the chamber can comprise a pipe extending from the proximal end to the distal end of the body. The pipe is preferably non-linear. In one embodiment, the inlet can be positioned at least partially further outwardly from the longitudinal axis of the body relative to the outlet. In this embodiment, the collar can be non-symmetrical about its longitudinal axis.

The distal end of the elongate member is preferably firstly inserted into the cochleostomy of the implantee during placement of the implant.

The chamber in the body can act as a reservoir for a bio-active substance. In one embodiment, the bio-active substance in the reservoir can leach from the chamber into the implantee. In one embodiment, the outlet can have a semi-permeable membrane. The membrane preferably allows the bioactive substance to leach from the chamber during and/or following implantation to the desired site of action for the bio-active substance.

Where the bio-active substance is carried in or comprises a fluid, the semi-permeable membrane preferably allows the fluid to leach or diffuse therethrough.

The membrane can act as a valve means that allows fluid to exit the chamber but prevents, or at least substantially prevents, fluid flow from external the chamber back into the chamber within the body.

In a further embodiment, the inlet of the body can be in communication, such as fluid communication, with an additional reservoir for the bio-active substance that is external or internal the body of the implantee. A catheter can extend from the inlet to the additional reservoir. A pump, such as an osmotic pump, can transfer the bio-active substance from the additional reservoir into the chamber of the body for subsequent delivery to the appropriate site of action.

It is also envisaged that the bio-active substance can be captured in the form of a solid or semi-solid pellet. In one embodiment, the pellet can be formed by impregnating the bio-active substance in a ceramic or a polymer pellet that has a predetermined rate of release of the bioactive substance. This solid pellet can then be stored in the chamber or in an external reservoir connectable to the chamber.

In one embodiment, the bioactive substance can comprise a steroid. In another embodiment, the bioactive substance can perform a function of reducing the resting neuron potential of neurons within the cochlea. The use of such substances can result in less energy being required to excite the neurons and cause stimulation.

In a further embodiment, the elongate member of the stimulating device has a plurality of electrodes mounted thereon. The member can have a diameter of about 0.6mm. The member can also have a first configuration selected to allow said member to be inserted into an implantee's body, such as the cochlea, and a second configuration wherein said elongate member is adapted to apply a preselected tissue stimulation with the electrodes. In a further embodiment, the elongate member can have at least one intermediate configuration between said first and second configurations.

In a still further embodiment, at least a portion of the outer surface of the elongate member can have a coating of lubricious material. In a further embodiment, a substantial portion of the outer surface can have a coating of the lubricious material. In a still further embodiment, the entire outer surface of the elongate member can have a coating of the lubricious material.

The lubricious material preferably becomes lubricious on being brought into contact with a fluid, such as a saline solution. Still further, the coating preferably becomes lubricious on being brought into contact with a body fluid, such as cochlear fluid.

In one embodiment, the lubricious material is selected from the group comprising polyacrylic acid (PAA), polyvinyl alcohol (PVA), polylactic acid (PLA) and polyglycolic acid (PGA). It is envisaged that other similar materials

could also be used. It is envisaged that the lubricious material can also be impregnated with the bio-active substance allowing the coating to perform a dual role. The rate of delivery of the bio-active substance can be programmed by design of the coating structure.

In yet another embodiment, the device can include a stiffening element made of a second material relatively stiffer than the resiliently flexible material of the elongate member. The stiffening element can be adapted to bias the elongate member into the first configuration.

In a preferred embodiment, the second configuration of the elongate member is curved. More preferably, the elongate member adopts a spiral configuration when in the second configuration.

The elongate member is preferably preformed from a plastics material with memory and is preformed to the second configuration. In a preferred embodiment, the first configuration is preferably substantially straight. More preferably, the first configuration is straight.

In a preferred embodiment, the elongate member is formed from a suitable biocompatible material. In one embodiment, the material can be a silicone, such as Silastic MDX 4-4210, Rhodia or Nusil silicones. In another embodiment, the elongate member can be formed from a polyurethane or similar material.

In one embodiment, the stiffening element can comprise a metallic stylet, or a stylet-like element formed from any other suitable stiffening material, extending through a lumen in the elongate member. In one embodiment, the wire can be formed from a biocompatible metal, a biocompatible metallic alloy or a biocompatible relatively stiff plastic. In a preferred embodiment, a metal stylet can be formed from platinum.

The present invention provides a surgeon with an implantable component of a cochlear implant electrode array that can assist with the delivery of one or more bio-active substances to a position external the site of the cochleostomy during and/or following implantation of the component. The

substances that can be delivered by the present device include substances that are adapted to promote healing, substances that prevent bleeding or at least excessive bleeding, substances that prevent the growth of tissue, including scar tissue, in the cochlea following implantation, and neural growth stimulation factors. Pharmaceutical compounds such as anti-inflammatories and antibiotics can also be delivered by the present device.

It is also envisaged that substances that assist in reducing the resting potential of the surrounding neurons can also be delivered by the present invention. It should be appreciated that during neural stimulation the neurons propagate an action potential through the response of transmembrane ion channels to local electrical fields. By delivering a substance that elicits a change in the transmembrane potential, the resting neural membrane potential can be moved towards the activation potential resulting in a lowering of the energy required to be delivered to activate the neuron. This also has the potential to reduce the power required by the stimulation device as well as increase the specificity of the electrical stimulation and restore the stochastic response of the neurons.

The device can be adapted to only provide delivery of a bio-active substance to the preferred site for a particular period following implantation. This period may comprise any period of time from a few hours or days to a few weeks or even months. In another embodiment, the device can be used as a means of delivery of bio-active substances to the implantee well beyond the time of implantation. For example, the additional reservoir can be periodically filled with a bio-active substance to ensure continued supply of the bio-active substance to the implantation site. The additional reservoir, in this case, may be positioned beneath but adjacent the surface of the skin of the implantee thereby allowing the reservoir to be filled by a syringe and needle assembly that injects the bio-active substance into the additional reservoir.

Once implanted, the electrodes can receive stimulation signals from a stimulator device. The stimulator device is preferably electrically connected to the elongate member by way of the electrical lead. The lead can include the one or more wires extending from each electrode of the array mounted on the elongate member.

In one embodiment, the lead can extend from the elongate member to the stimulator device or at least the housing thereof. In one embodiment, the lead is continuous with no electrical connectors, at least external the housing of the stimulator means, required to connect the wires extending from the electrodes to the stimulator means. One advantage of this arrangement is that there is no requirement for the surgeon implanting the device to make the necessary electrical connection between the wires extending from the electrodes and the stimulator means. In this case, the body of the substance delivery means is preferably positioned around the lead prior to attachment of the lead to the stimulator device.

The stimulator device is preferably positioned within a housing that is implantable within the implantee. The housing for the stimulator device is preferably implantable within the bony well in the bone behind the ear posterior to the mastoid.

When implantable, the housing preferably contains, in addition to the stimulator device, a receiver device. The receiver device is preferably adapted to receive signals from a controller means. The controller means is, in use, preferably mounted external to the body of the implantee such that the signals are transmitted transcutaneously through the implantee.

Signals can preferably travel from the controller means to the receiver device and vice versa. The receiver device can include a receiver coil adapted to receive radio frequency (RF) signals from a corresponding transmitter coil worn externally of the body. The radio frequency signals can comprise frequency modulated (FM) signals. While described as a receiver coil, the receiver coil can preferably transmit signals to the transmitter coil which receives the signals.

The transmitter coil is preferably held in position adjacent the implanted location of the receiver coil by way of respective attractive magnets mounted centrally in, or at some other position relative to, the coils.

The external controller can comprise a speech processor adapted to receive signals output by a microphone. During use, the microphone is preferably worn on the pinna of the implantee, however, other suitable locations can be envisaged, such as a lapel of the implantee's clothing. The speech processor encodes the sound detected by the microphone into a sequence of electrical stimuli following given algorithms, such as algorithms already developed for cochlear implant systems. The encoded sequence is transferred to the implanted receiver/stimulator device using the transmitter and receiver coils. The implanted receiver/stimulator device demodulates the FM signals and allocates the electrical pulses to the appropriate attached electrode by an algorithm which is consistent with the chosen speech coding strategy.

The external controller further comprises a power supply. The power supply can comprise one or more rechargeable batteries. The transmitter and receiver coils are used to provide power via transcutaneous induction to the implanted receiver/stimulator device and the electrode array.

According to a further aspect, the present invention is a method of delivering at least one bioactive substance to a desired site of action adjacent a cochleostomy within a patient using a device as defined herein, the method comprising the steps of:

forming a cochleostomy;

inserting the elongate member through the cochleostomy;

closing the cochleostomy; and

slidably positioning the body of the bio-active substance delivery means adjacent the cochleostomy and allowing bio-active substances to exit therefrom.

Brief Description of the Drawings

By way of example only, a preferred embodiment of the invention is now described with reference to the accompanying drawings, in which:

Fig. 1 is a pictorial representation of a prior art cochlear implant system;

Fig. 2 is a simplified cross-sectional view of one embodiment of an electrode assembly according to the present invention;

Fig. 2a is a cross-sectional view of the device of Fig. 2 through line AA;

Fig. 2b is a cross-sectional view of the device of Fig. 2 through line BB;

Fig. 3 is simplified cross-sectional view of another embodiment of a device according to the present invention;

Fig. 3a is a cross-sectional view of the device of Fig. 3 through line AA; and

Fig. 3b is a cross-sectional view of the device of Fig. 3 through line BB.

Preferred Mode of Carrying out the Invention

Before describing the features of the present invention, it is appropriate to briefly describe the construction of one type of known cochlear implant system with reference to Fig. 1.

Known cochlear implants typically consist of two main components, an external component including a speech processor 29, and an internal component including an implanted receiver and stimulator unit 22. The external component includes a microphone 27. The speech processor 29 is, in this illustration, constructed and arranged so that it can fit behind the outer ear 11. Alternative versions may be worn on the body. Attached to the speech processor 29 is a transmitter coil 24 which transmits electrical signals to the implanted unit 22 via a radio frequency (RF) link.

The implanted component includes a receiver coil 23 for receiving power and data from the transmitter coil 24. A lead 21 extends from the implanted receiver and stimulator unit 22 to the cochlea 12 and terminates in an electrode array 20 that is passed through a cochleostomy and into the cochlea 12. The signals thus received are applied by the array 20 to the basilar membrane 8 and the nerve cells within the cochlea 12 thereby stimulating the auditory nerve

9. The operation of such a device is described, for example, in US Patent No. 4532930, the contents of which are incorporated herein by reference.

One embodiment of a cochlear implant electrode assembly incorporating a system for delivery of bio-active substances is depicted generally as 30 in Fig. 2.

The depicted electrode assembly 30 has an electrical lead 21 extending back to a receiver/stimulator housing, such as the stimulator unit 22 depicted in Fig. 1. In considering this invention, it is to be understood that each electrode 32 may have one or more wires (not depicted) electrically connected thereto and extending from each respective electrode 32 back through the lead to the receiver/stimulator unit 22.

The assembly 30 comprises an elongate electrode carrier member 31 having a plurality of electrodes 32 mounted thereon. For the purposes of clarity, the electrodes 32 depicted in Fig. 2 are not necessarily shown to scale. A larger or indeed smaller number of electrodes than that depicted in Fig. 2 can also be envisaged.

While depicted as being straight, the depicted elongate member 31 can be preformed from a resiliently flexible silicone with memory to a curved configuration suitable for insertion in the scala tympani of a human cochlea 20.

The elongate member 31 has a distal end 33 that is firstly inserted into the cochlea 12 upon insertion of the assembly 30.

As depicted in Fig. 2, a collar 40 is slidably disposed around the lead 21. The collar 40 is part of a system for delivering one or more pharmaceutical or bioactive substances to a location just external the cochleostomy of the cochlea 12.

In Fig. 2, the collar 40 can be moved along the lead 21 towards the distal end 33 of the array member until it reaches a stop member that prevents further slidable movement of the collar in that direction.

The collar 40 has a stepped outer surface 41 defined by two cylindrical portions 42 and 43. In the depicted embodiment, the collar 40 is symmetrical about its longitudinal axis and has parallel proximal and distal ends 44,45.

The outlet 46 of the collar 40 is positioned in the distal end 45 of the collar 40. In the depicted embodiment, the collar 40 further has an inlet 50 in the proximal end 44 of the collar 40. The inlet and outlet are in communication, such as fluid communication, with each other.

As depicted in Fig. 2, the outlet 46 of the collar 40 comprises an annular opening in the distal end 45 of the collar. The chamber 47 within the collar extends back into the collar 40 from the outlet 46. As the depicted outlet 46 is an annular opening, the chamber 47 is also annular in form and so comprises a cylindrical chamber having an outer and inner surface and extending back into the collar from the outlet 46. It will be appreciated, however, that the outlet and chamber need not be annular to fall within the scope of the present application.

The annular chamber 47 has a frusto-conical region 48 where the outer and inner walls of the chamber 47 move away from the longitudinal axis of the collar 40, and a further cylindrical region 49 distal the outlet. In this embodiment, the inlet 50 comprises a pipe extending from the proximal end 44 of the collar into the chamber 47. The inlet 50 is adjacent the outer wall 41 of the collar 40.

A different construction of a collar is generally depicted as 60 in Figs. 3, 3a and 3b. As depicted, the chamber can instead comprise a non-linear pipe 61 extending from the proximal end 44 to the distal end 45 of the collar 60. The inlet 50 is positioned at least partially further outwardly from the longitudinal axis of the collar 60 body relative to the outlet 46.

The distal end of the elongate member is preferably firstly inserted into the cochleostomy of the implantee during placement of the implant.

The chamber in the collar acts as a reservoir for a bio-active substance. This bio-active substance in the chamber diffuses from the chamber into the implantee through a semi-permeable membrane 70 in the outlet 46. The

membrane 70 allows the bioactive substance to leach from the chamber during and/or following implantation to the desired site of action for the bio-active substance.

Where the bio-active substance is carried in or comprises a fluid, the semi-permeable membrane 70 allows the fluid to leach or diffuse therethrough.

The membrane 70 can act as a valve means that allows fluid to exit the chamber but prevents, or at least substantially prevents, fluid flow from external the chamber back into the chamber within the body.

A catheter 80 can extend from the inlet 50 to an additional reservoir for a bio-active substance. A pump, such as an osmotic pump, can transfer the bio-active substance from the additional reservoir into the chamber of the body for subsequent delivery to the appropriate site of action.

It is also envisaged that the bio-active substance can be captured in the form of a solid or semi-solid pellet. In one embodiment, the pellet can be formed by impregnating the bio-active substance in a ceramic or a polymer pellet that has a predetermined rate of release of the bioactive substance. This solid pellet can then be stored in the chamber or in an external reservoir connectable to the chamber.

In one embodiment, the bioactive substance can comprise a steroid. In another embodiment, the bioactive substance can perform a function of reducing the resting neuron potential of neurons within the cochlea. The use of such substances can result in less energy being required to excite the neurons and cause stimulation.

The provision of a system for delivering a pharmaceutical substance, just external the site of a cochleostomy, that promotes healing and/or more efficient neural stimulation while preventing the formation of substantial scar tissue in the cochlea, enhances the likelihood of successful long-term placement of the assembly 30 in the cochlea and subsequent successful use of the cochlear implant by the implantee.

While the preferred embodiment of the invention has been described in conjunction with a cochlear implant, it is to be understood that the present invention has wider application to other implantable electrodes, such as electrodes used with pacemakers.

It will be appreciated by persons skilled in the art that numerous variations and/or modifications may be made to the invention as shown in the specific embodiments without departing from the spirit or scope of the invention as broadly described. The present embodiments are, therefore, to be considered in all respects as illustrative and not restrictive.

Dated this twenty ninth day of November 2002

Cochlear Limited
Patent Attorneys for the Applicant:

F B RICE & CO

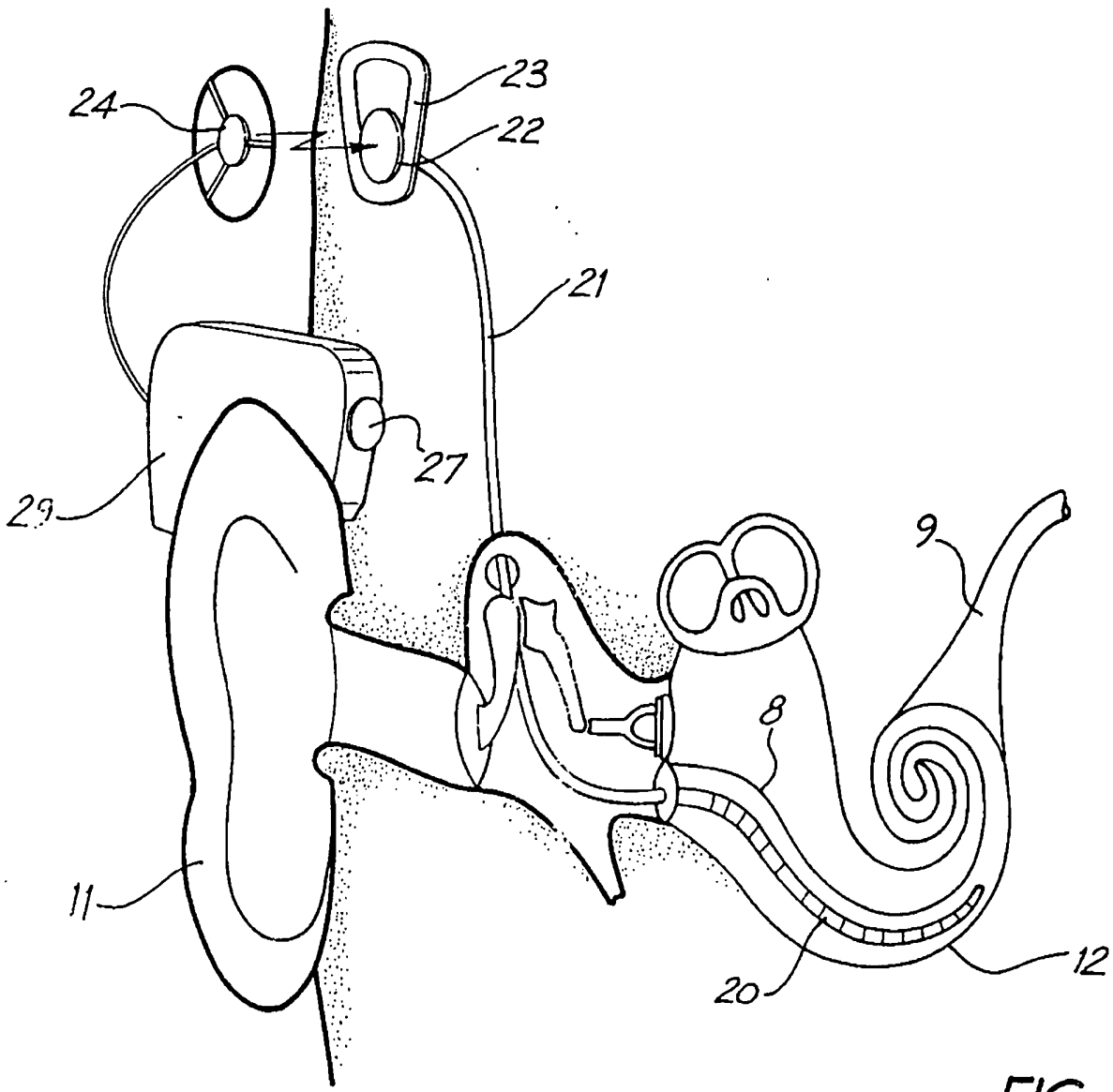

FIG. 1

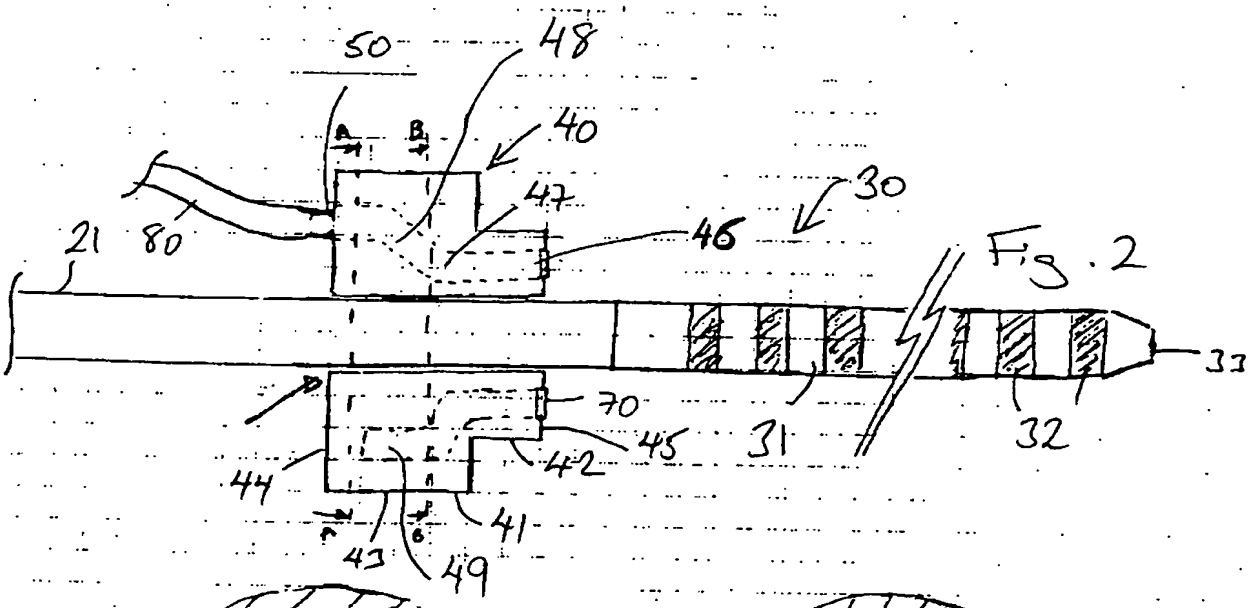

Fig. 2

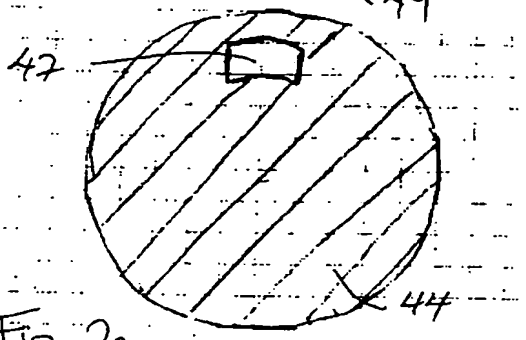

Fig. 2a

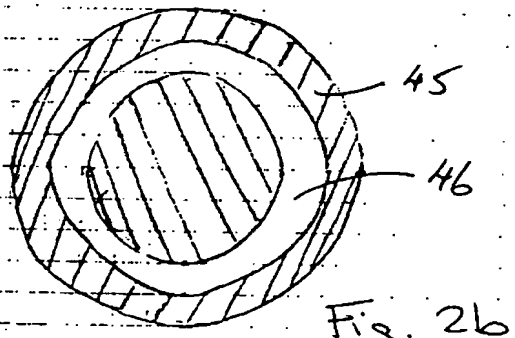

Fig. 2b

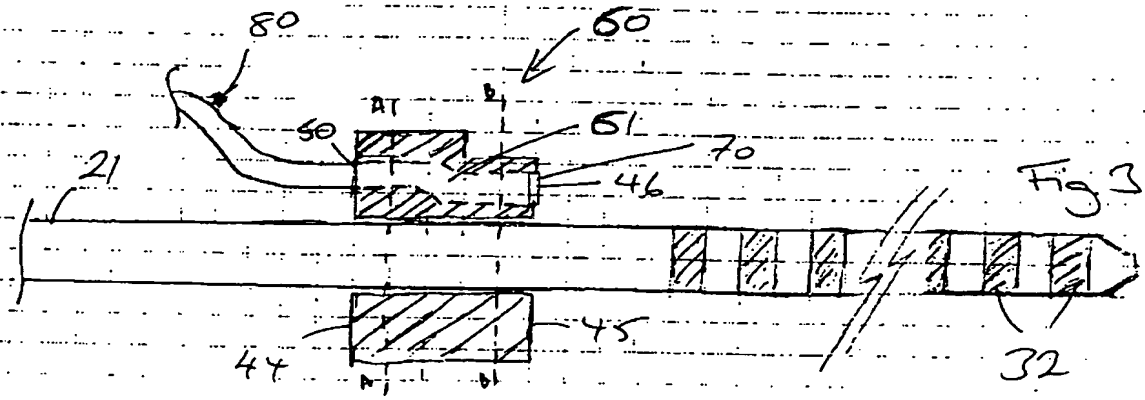

Fig 3

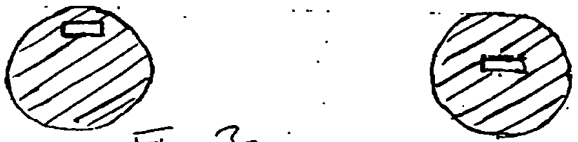

Fig. 3a

Fig. 3b